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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,670	12/30/2005	Eswaran Krishnan Iyer	WH-3	6215

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EXAMINER	
PURDY, KYLE A	
ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,670	IYER ET AL.	
	Examiner	Art Unit	
	Kyle Purdy	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/03/2005 and 01/11/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-72* is/are pending in the application.

4a) Of the above claim(s) *14-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1 sheet (05/03/2005)*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election Acknowledged

1. Applicant's election with traverse of the invention of Group I encompassing claims 1-13 in the reply filed on January 11, 2007 is acknowledged. The traversal is on the ground(s) that Groups I-V do not pose a serious burden on the examiner as Groups I-V are all directed to a pharmaceutical composition comprising A) a slow release therapeutic agent; B) another slow or immediate release therapeutic agent belonging to a class of drugs not similar to the one covered under component A; and C) a slow or immediate release therapeutic agent belonging to a class of drugs not similar to the ones covered under either A or B. Applicant also argues that the subject matter of Groups I-V are all within the same class and subclass. These arguments are not found persuasive because an application may be properly required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are either independent or distinct. See MPEP 803. For example, Group I Applicant is claiming a composition comprising biguanide, a sulfonylurea and a glitazone whereas Group II requires a biguanide, an ACE inhibitor and aspirin. The compositions are mutually exclusive and the search of one would not be coextensive with the other. Applicant has multiple inventions directed to compositions comprising widely divergent subject matter that varies from aspirin to sulfonylureas. Therefore, as none Groups II-V require the same essential components as Group I to function, it follows that the restricted claims are not only distinct over one another, but can also support separate patents.

2. The requirement is still deemed proper and is therefore made FINAL.

Applicants' Invention

3. Applicants have claimed a pharmaceutical composition and a kit thereof wherein the composition comprises A) a slow release therapeutic agent as one of components; B) another slow or immediate release therapeutic agent belonging to a class of drugs not similar to the one covered under component A; and C) a slow or immediate release therapeutic agent belonging to a class of drugs not similar to the ones covered under either A or B wherein A) is a biguanide, B) is a sulfonylurea and C) is a glitazone. The composition may take the form of a tablet or capsule and the components may be separate from on another.

Claim Objections

4. Claims 7 and 11 are objected to because of the following informalities: improper use periods and a lack thereof, respectively. Claim 7 improperly uses a period at the end of tab a). Claim 10 fails to include a period at the end of the sentence. See MPEP 608.01(m). Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. **Claims 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

7. Claim 7 is a method claim which recites, "A method of treatment using a pharmaceutical composition of claim 1, which when ingested by human a)reduced the C_{max} by at least 10-15% for the slow release component relative to the corresponding immediate release component; b)Increases .....". It appears that Applicant is intending to describe the properties of the composition rather than setting forth any specific method steps. In the case of a method or process, claim scope is not limited by claim language that does not require steps to be performed. See MPEP 2111.04. It is unclear what Applicant is intending to claim and so the Examiner is interpreting the claim to be method of ingesting (or administering) the composition of claim 1 to a patient. Clarification is required.

8. Claim 8 is a composition claim which recites, 'A therapeutically effective amount of a pharmaceutical composition of claim 1 which allows a reduction in the dosing regimen of any one of the individual agents'. With respect to the phrase 'allows a reduction in the dosing regimen of any one of the individual agents', specifically what agent? Furthermore, what would sufficiently encompass a reduction? Would removing the compound entirely from the composition qualify as a reduction? Clarification is required.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. **Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitcomb (US 6011049) in view of Pearson et al. (US 2003/0078269).**

12. Whitcomb ('Whitcomb) discloses a pharmaceutical combination for treating diabetes wherein the combination includes a glitazone (such as trolitazone, see column 2, lines 30-40; see instant claim 3), a biguanide (such as metformin, see column 3, lines 33-35; see instant claim 3) and a sulfonylurea (such as glipizide, see column 2, lines 5-6; see instant claim 3). It is taught that the therapeutic composition consisting of a glitazone, a biguanide and a sulfonylurea are especially useful for treating diabetes and associated complications such as cardiovascular disease and retinopathy (see column 1, lines 20-39; see instant claims 1-5). The mode by which the compounds are administered includes a single triple-combination dosage or individually (i.e. physically separated) as performed clinically, and exemplified dosage forms include tablets, capsules as well as controlled release formulations (see column 4, lines 35-40; see instant claims 6 and 9-11). The method of administering the composition to a patient is described in claim 8 (see instant claim 7).

13. The teaching of Whitcomb fails to teach the glycemic regulatory composition comprising a glitazone, a biguanide and a sulfonylurea where at least one or two of the components are released at a sustained and/or rapid rate.

14. The teaching of Pearson et al. ('Pearson) is drawn to biguanide and sulfonylurea formulations for treating insulin resistance and type II diabetes (see abstract). Pearson notes that that four classes of glycemic regulators are currently available that include biguanides, sulfonylureas, alpha-glucosidase inhibitors, and thiazolidinediones (glitazone) (see [0145]). It is taught that the composition comprising a biguanide and sulfonylurea can be carried by a delivery vehicle which may comprise one or more active agents which release the agents either by immediately dispersing the agents in the stomach or by releasing the agents in a sustained fashion in the intestine, wherein the delivery vehicle includes tablets and capsules (see [0597] and [0617]; see instant claim 13). The term 'sustained release' is meant to describe the rate at which the biguanide and/or the sulfonylurea is released from the delivery vehicle, which typically ranges from about thirty minutes to about 3 days. Moreover, it is taught the rate of release is dependent upon many factors such as particle size, composition, the acidity of the environment and the solubility of the active agent in the physiological environment (see [0598]).

15. Therefore, it would have been obvious to one ordinarily skilled in the art at the time the invention was made to combine the teachings of Whitcomb and Pearson with a reasonable expectation of success in arriving at a multi-component composition that includes a biguanide, a glitazone and a sulfonylurea capable of effectively treating diabetes and cardiovascular conditions. The significance of Whitcomb is that is teaches a synergistic composition which includes a glitazone, a biguanide and a sulfonylurea capable of treating diabetes. Whitcomb

demonstrated that the triple combination resulted in improved treatment of diabetic symptoms such as improved glucose and triglyceride levels as opposed to the use of the compounds individually or use of a combination of two such as sulfonylurea/biguanide (see column 16, lines 36-50). With respect to the instant claims limitation that the composition is to be used for treating cardiovascular disorders (see instant claim 5) is inherent to the combination of the specific compounds, that is, such a composition will always have such a property. The teaching of Whitcomb also teaches that the composition can be formulated to be a slow-release tablet or capsule, but fails to expressly teach that any of the components are rapid or immediately released upon ingestion. The teaching of Pearson cures these deficiencies. Pearson is drawn to treating diabetes with a composition comprising a combination of biguanide and sulfonylurea which may be administered through slow- and/or rapid-release mechanisms. It would be obvious to use the slow and rapid release principles required by Pearsons glycemic regulatory composition and apply them to Whitcomb because in doing so one skilled in the art would arrive at a product possessing the properties instantly claimed. With respect to the claims recitation of specific properties such as the rate of 'in-vitro release' (for example, see claim 12), no patentable weight is given because it would be obvious to one ordinarily skilled in the art to optimize and alter the properties such as particle size and solubility of the active agent (see above) for the dosage form such that the rate of release would correspond to the greatest therapeutic efficacy. When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Therefore, the invention as a whole is *prima facie* obvious to one ordinarily skilled in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle Purdy/
Examiner, Art Unit 1611

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